

EXHIBIT KK

Nos. 22-354, 22-374
United States Court of Appeals for the Second Circuit

BIONPHARMA INC.,
PLAINTIFF-APPELLEE

v.

CORERX, INC.,
DEFENDANT-APPELLANT

v.

AZURITY PHARMACEUTICALS, INC.,
INTERVENOR- APPELLANT

*APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK, NO. 1:21-CV-10656 (JGK)*

**INTERVENOR-APPELLANT AZURITY PHARMACEUTICALS, INC.’S
RESPONSE TO PLAINTIFF-APPELLEE BIONPHARMA INC.’S
MOTION FOR JUDICIAL NOTICE AND FURTHER REPLY
IN SUPPORT OF ITS EMERGENCY MOTION FOR A STAY**

ELI B. RICHLIN

*Wilson Sonsini Goodrich & Rosati, P.C.
1301 Avenue of the Americas
New York, NY 10019
(212) 999-5800*

Counsel for Intervenor-Appellant Azurity Pharmaceuticals, Inc.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, counsel for Intervenor-Appellant Azurity Pharmaceuticals, Inc. states that Azurity Pharmaceuticals, Inc. is a wholly-owned subsidiary of CurtisPharma Intermediate Holdings Inc. and that no publicly traded company hold more than 10% of its stock.

Dated: March 14, 2022

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI
Professional Corporation

/s/ Eli B. Richlin

ELI B. RICHLIN

*Counsel for Intervenor-Appellant
Azurity Pharmaceuticals, Inc.*

TABLE OF CONTENTS

	<u>Page</u>
CORPORATE DISCLOSURE STATEMENT	i
BACKGROUND	1
ARGUMENT	2
I. A stay of the preliminary injunction will prevent irreparable harm to Azurity, notwithstanding Azurity's launch of an authorized generic.	2
II. Azurity is likely to prevail on the merits, notwithstanding the Federal Circuit's affirmance in a separate litigation.	4
CONCLUSION.....	6

Intervenor-Appellant Azurity Pharmaceuticals, Inc. (“Azurity”) does not oppose Plaintiff-Appellee Bionpharma Inc.’s (“Bionpharma”) motion for judicial notice. Case No. 22-374 (2d Cir.), Dkt. No. 65. Azurity writes only to clarify that a stay of the preliminary injunction granted below remains critical, notwithstanding the new developments raised by Bionpharma.

BACKGROUND

On January 27, 2022, the district court below granted a preliminary injunction, requiring Defendant-Appellant CoreRx, Inc. (“CoreRx”) to provide Bionpharma a pharmaceutical product that infringes Azurity’s valid patents. Case No. 1:21-cv-10656-JGK (S.D.N.Y.), Dkt. No. 50. On February 24, 2022, the district court granted Azurity’s motion to intervene for the limited purpose of appealing the preliminary injunction and denied CoreRx’s motion to stay the preliminary injunction. Case No. 1:21-cv-10656-JGK (S.D.N.Y.), Dkt. No. 105. On March 2, 2022, this Court denied Azurity’s and CoreRx’s request for an administrative stay of the preliminary injunction, and referred Azurity’s and CoreRx’s motion to stay the preliminary injunction to a three-judge motions panel. Case No. 22-374 (2d Cir.), Dkt. No. 30. On March 7, 2022, the stay motion was added as a submitted case to the substantive motions calendar for March 15, 2022. Case No. 22-374 (2d Cir.), Dkt. No. 52. On March 11, 2022, Bionpharma moved for judicial notice of two recent developments: (1) Azurity’s launch of an authorized generic pharmaceutical product, and (2) the Federal

Circuit's affirmance of a judgment that Bionpharma did not infringe certain of Azurity's patents. Case No. 22-374 (2d Cir.), Dkt. No. 65.

ARGUMENT

As noted, Azurity does not oppose Bionpharma's motion for judicial notice, but disagrees with Bionpharma's characterization of the impact of recent developments on Azurity's motion to stay and appeal. Neither development materially undercut Azurity's prior showing that a stay of the preliminary injunction is warranted.

I. A stay of the preliminary injunction will prevent irreparable harm to Azurity, notwithstanding Azurity's launch of an authorized generic.

Bionpharma argues that "harm that Azurity sought to avoid by a stay has already occurred because Azurity has launched its authorized generic." Case No. 22-374 (2d Cir.), Dkt. No. 65 at 3. This is misleading.

Azurity argued that it would suffer irreparable harm absent a stay of the preliminary injunction for two independent reasons: (1) Bionpharma and CoreRx are likely judgment-proof and therefore Azurity would be unable to recover damages against them to the extent that Bionpharma continues to sell its infringing product, and (2) Bionpharma's generic would force Azurity to launch an authorized generic, which would result in additional downward pricing pressure for Azurity's branded pharmaceutical product. Case No. 22-374 (2d Cir.), Dkt. No. 7 at 19-22; Dkt. No. 26 at 7-10.

Azurity's launch of an authorized generic has nothing to do with the first reason. Accordingly, a stay would still prevent significant irreparable harm to Azurity resulting from Bionpharma's and CoreRx's likely inability to compensate Azurity in damages for patent infringement.

Additionally, Bionpharma overstates the impact of Azurity's authorized generic on the second reason. A stay would still prevent irreparable harm to Azurity to the extent that a stay would reduce additional downward pricing pressure from Bionpharma's generic.

Bionpharma also argues that "if the Bionpharma product were removed from the market because of a supply shortage, Azurity could use an authorized generic to capture Bionpharma's market-share for itself." Case No. 22-374 (2d Cir.), Dkt. No. 65 at 3-4. Azurity launched its authorized generic to defend its own market share against nonparty Annora's generic that is infringing Azurity's valid patents—not to preemptively capture Bionpharma's market share. *See* Case No. 22-374 (2d Cir.), Dkt. No. 26 at 9. Moreover, Bionpharma's point is not a reason to deny the stay because Bionpharma never argued—much less proved—that it will run out of inventory during the pending of Azurity's appeal. Thus, Azurity could not "use an authorized generic to capture Bionpharma's market-share" if granted the stay.

II. Azurity is likely to prevail on the merits, notwithstanding the Federal Circuit’s affirmance in a separate litigation.

Bionpharma argues that the Federal Circuit’s affirmance of a judgment that Bionpharma did not infringe Azurity’s ’745 and ’987 patents implies that Azurity cannot prevail on the merits of its appeal. Case No. 22-374 (2d Cir.), Dkt. No. 65 at 4. This is wrong.

In its stay motion, Azurity made two independent arguments on the merits: (1) Azurity’s assertion of its ’023 and ’405 patents against CoreRx constitutes a “Supply Interruption” under the supply agreement between Bionpharma and CoreRx, and (2) Bionpharma failed to meet its burden of proof to establish that the supply agreement is a valid contract. Case No. 22-374 (2d Cir.), Dkt. No. 7 at 12-15; Dkt. No. 26 at 3-7.

The Federal Circuit’s affirmance is irrelevant to the first argument. Contrary to Bionpharma’s point, this argument is *not* “based on the premise that Azurity will prevail on its patent-infringement claims.” Case No. 22-374 (2d Cir.), Dkt. No. 65 at 4. To the contrary, the argument is based on the premise that the *assertion* of patent claims constitutes a “Supply Interruption” under the supply agreement. Case No. 22-374 (2d Cir.), Dkt. No. 7 at 14-15; Dkt. No. 26 at 5-7. Although Azurity is confident that it will prove infringement of its ’023 and ’405 patents, CoreRx need

not wait until it is enjoined to assert a Supply Interruption under the supply agreement.

Bionpharma also overstates the impact of the Federal Circuit's affirmance on Azurity's second argument. Bionpharma states that "affirmance of the judgment in Bionpharma's favor in the first case bears on Azurity's ultimate chance of prevailing in its patent cases as a whole." Case No. 22-374 (2d Cir.), Dkt. No. 65 at 4. Tellingly, however, Bionpharma fails to support this assertion, and it is wrong. The Federal Circuit affirmed a judgment that Bionpharma did not infringe two of Azurity's patents, the '745 and '987 patents. *See Azurity v. Bionpharma*, Case No. 21-1926, Dkt. No. 21 at 4 (Fed. Cir. Aug. 25, 2021). Azurity's pending cases allege patent infringement claims based on two *other, separate* patents, the '023 and '405 patents, not at issue in the Federal Circuit ruling. *See Azurity v. Bionpharma*, Case No. 1:21-cv-01286-LPS, Dkt. No. 1 (D. Del. filed June 22, 2021); *Azurity v. Bionpharma*, Case No. 1:21-cv-01455-LPS, Dkt. No. 1 (D. Del. filed Oct. 15, 2021). The '023 and '405 patents, which are currently being asserted against Bionpharma, were never reviewed by the Federal Circuit. Additionally, while Bionpharma prevailed on its non-infringement theories with respect to the '745 and '987 patents before the Federal Circuit, Bionpharma has not put forth a substantive non-infringement position with respect to the '023 and '405 patents. *See Azurity v. Bionpharma*, Case No. 1:21-cv-01286-LPS, Dkt. No. 96 at 60:1-9 (D. Del. Nov. 10, 2021). Indeed, Bionpharma

moved to dismiss Azurity's claims for infringement of the '023 patent on the basis that those claims were precluded by the judgment that Bionpharma had not infringed the '745 and '987 patents, and the District of Delaware denied that motion because the '023 patent "contains broader claims." *See id.* at 114:11-115:23. Thus, the Federal Circuit's ruling does not say anything about whether Bionpharma has infringed the '023 and '405 patents, and consequently does not establish that Bionpharma has met its burden of proof regarding these two patents, which are presumed valid, 35 U.S.C. § 282. Azurity remains likely to prevail on the merits of its appeal.

CONCLUSION

Azurity does not oppose Biopharma's motion for judicial notice. But this Court should grant Azurity's motion to stay the preliminary injunction, notwithstanding the developments raised in Bionpharma's motion.

Respectfully submitted,

/s/ Eli B. Richlin

ELI B. RICHLIN

*Wilson Sonsini Goodrich & Rosati, P.C.
1301 Avenue of the Americas
New York, New York 10019
(212) 999-5800*

Counsel for Intervenor-Appellant Azurity Pharmaceuticals, Inc.

MARCH 14, 2022

CERTIFICATE OF COMPLIANCE

I hereby certify that:

1. This document complies with Fed. R. App. P. 27(d)(2) because it contains 1,244 words, excluding the parts of the document exempted by Fed. R. App. P. 32(f).
2. This document complies with the typeface and type-style requirements of Fed. R. App. P. 27(d)(1)(E) because it has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in 14-point font.

MARCH 14, 2022

/s/ Eli B. Richlin

ELI B. RICHLIN

CERTIFICATE OF SERVICE

I, Eli Richlin, hereby certify under penalty of perjury that on March 14, 2022, I caused to be served a copy of this Response to Motion for Judicial Notice and Further Reply in Support of Emergency Motion for a Stay on all parties by filing it with the Court's electronic filing system.

/s/ Eli B. Richlin

ELI B. RICHLIN